Medical Test Site (MTS) Application Packet

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Important Information:

Laboratories licensed by the Washington Medical Test Site (MTS) licensure program are exempt from the Clinical Laboratory Improvement Amendments of 1988 (CLIA). You do not need to apply to the Centers for Medicare and Medicaid Services (CMS) for a CLIA number. Your MTS license will contain both your MTS license number and your CLIA number.

In facilities, such as hospitals, where testing may be performed at different locations, all areas of laboratory testing must be covered by an MTS license. It is the facility's choice whether to include point of care (ancillary) testing under the same MTS license as the main laboratory, or license separately.

If you are applying for an Accredited license, your MTS must be inspected by the accreditation organization. Proof of accreditation or certification by the accreditation organization must be included with your application along with documentation for qualifications of the Laboratory Director.

If your MTS is located in a facility accredited by the Joint Commission, you have the option of being licensed as a Categorized Medical Test Site and inspections will be performed by the Washington State Medical Test Site (MTS) Program.

Per WAC 246-338-050, all licensed medical test sites, excluding those granted a certificate of waiver, must enroll in proficiency testing for all CMS regulated analytes.

In order to process your request:

Mail your application with initial documentation and your check or money order payable to:

Department of Health
P.O. Box 1099
Olympia, WA 98507-1099

Contact Us:
360-236-4985

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Fee Information

Submit the fee corresponding to the category of license, volume of tests, and date of application submission.

Licenses will expire on June 30, 2027. You will receive a renewal notice approximately 60 days before the expiration of the license

		Applications submitted 7/01/2025 to 6/30/2026	Applications submitted 7/01/2026 to 6/30/2027
Category of License	Test Volume	Fee	Fee
Certificate of Waiver	N/A	$260	$130
Provider Performed Microscopic Procedures (PPMP)	N/A	$300	$150
Categorized, Low Volume	1-2,000 tests	$620	$310
Categorized, Category A	2,001-10,000 tests, 1-3 specialties	$1,900	$950
Categorized, Category B	2,001-10,000 tests, 4 or more specialties	$2,450	$1,225
Categorized, Category C	10,001-25,000 tests, 1-3 specialties	$3,410	$1,705
Categorized, Category D	10,001-25,000 tests, 4 or more specialties	$3,910	$1,955
Categorized, Category E	25,001-50,000 tests	$4,700	$2,350
Categorized, Category F	50,001-75,000 tests	$5,810	$2,905
Categorized, Category G	75,001-100,000 tests	$6,930	$3,465
Categorized, Category H	100,001-500,000 tests	$8,090	$4,045
Categorized, Category I	500,001-1,000,000 tests	$14,390	$7,195
Categorized, Category J	> 1,000,000 tests	$17,260	$8,630
Accredited, Low Volume	1-2,000 tests	$230	$115
Accredited, Category A	2,001-10,000 tests, 1-3 specialties	$290	$145
Accredited, Category B	2,001-10,000 tests, 4 or more specialties	$320	$160
Accredited, Category C	10,001-25,000 tests, 1-3 specialties	$730	$365
Accredited, Category D	10,001-25,000 tests, 4 or more specialties	$780	$390
Accredited, Category E	25,001-50,000 tests	$1,090	$545
Accredited, Category F	50,001-75,000 tests	$1,740	$870
Accredited, Category G	75,001-100,000 tests	$2,390	$1,195
Accredited, Category H	100,001-500,000 tests	$3,090	$1,545
Accredited, Category I	500,001-1,000,000 tests	$8,920	$4,460
Accredited, Category J	> 1,000,000 tests	$11,330	$5,665

Medical Test Site
Application Instructions Checklist

You will be notified in writing of any outstanding documentation needed to complete the application process. Application processing may be delayed if the required information is missing.

☐ **Application Type:**

- **New License** - Choose this option if you have never been issued an MTS license.
- **Change of License Type** - Choose this option if you have an MTS license and want to change the type of license you have. A new MTS license number will be issued. You will keep the current CLIA number.
- **Change of Ownership** - Choose this option if your MTS will be operating under new ownership. A new MTS license number will be issued. You must notify DOH right away of changes to the proposed date the change of ownership will occur.
- **Expired or Closed Credential Reactivation** - Choose this option if you are reactivating an expired or closed MTS license.

☐ **License Type**

Verify what type of test you are using by searching the test categorization database.

Waived license: Choose this option if only waived medical tests will be performed. A list of commonly used waived tests is available.

PPMP license: Choose this option if only waived medical tests and any of the nine approved microscopic procedures listed in WAC 246-338-020 will be performed.

Categorized license: Choose this option if your MTS will perform tests the FDA classifies as either moderate or high complexity in addition to waived tests and want to be inspected by the Department of Health.

Accredited license: Choose this option if your MTS will perform tests the FDA classifies as either moderate or high complexity in addition to waived tests and want to be inspected by an accreditation organization listed in WAC 246-338-040. You must apply separately to the accreditation organization.

☐ **Entity Type:**

Please check your legal owner/operator business structure type according to your Washington State Master Business License.

☐ **Section 1 - Demographic Information:**

Unified Business Identifier Number (UBI #): Enter your Washington State UBI #. You must have a UBI # to operate a business in Washington.

Federal Employer ID Number (FEIN): Enter your FEIN (also known as a tax ID number).

Legal Owner/Operator Name: Enter the owner's name as it appears on the UBI/ Master Business License.

Legal Owner Mailing Address: Enter the owner's complete mailing address.

Phone and Fax: Enter the owner's phone and fax numbers.

Email and Web Address: Enter the owner's email and facility web addresses, if applicable.

Facility/Agency Name: Enter the name of the MTS as advertised on signs and web site.

Facility Specific Federal Employer ID Number (FEIN). Enter if different from the Owner FEIN listed on page one of the application.

Physical Address: Enter the physical street location of the MTS including city, state, zip code, and county.

Phone and Fax Numbers: Enter the phone and fax number.

Mailing Address: Enter the mailing address, if different than the physical address. Your MTS Certificate will be mailed to this address.

☐ **Section 2 - Facility Specific Information:**
Type of Medical Test Site: Please check one applicable site type.

Hours of Laboratory Testing: Check the box if the MTS is open 24 hours a day. Otherwise, list the hours testing is performed.

Additional locations under this license: If your MTS qualifies for a multiple site exception under WAC 246-338-022, check yes and attach a list of names, addresses and phone numbers for the additional locations. Provide a list of tests performed at each site.

Foreign Ownership: Indicate whether the facility is owned fully or partially by a foreign entity.

Testing Complexity: Required only for applicants applying for a Categorized or Accredited MTS license, indicate the highest complexity level of patient testing.

☐ **Section 3 - Key Individuals:**
Lab Director: Enter the lab director's first name, last name, Washington State professional license number (if applicable), and email address. If the lab director has a professional license, submit a copy of their license.

Additional Contact Person: Enter the lab contact's first name, last name, and email address.

☐ **Section 4 - Waived Test Information:**
Fill in the test system and test manufacturer in the provided table for each test your lab performs. Refer to the CLIA waived test list provided by the FDA to verify the test you are using is approved for waived use.

☐ **Section 5 - Provider-Performed Microscopic Procedures (PPMP) Test Information:**
PPMP Tests: The microscopic procedures can only be performed in your facility by a Washington State licensed MD, DO, DPM, ARNP, PA, or Dentist. Indicate which tests will be performed.

☐ **Section 6 - Nonwaived Test Information:**

Place a checkmark by all nonwaived tests performed at your medical test site. If the tests are not listed, add the tests under the appropriate specialty/subspecialty (bold headings).

Provide an estimate of the annual volume of tests to be performed. Attach additional sheets if needed. Do not include waived or PPMP tests when counting volumes.

Tests listed in bold require enrollment in proficiency testing. Submit a list of programs you will enroll in for proficiency testing.

Use the following guidelines for counting tests:

Allergens: count each individual allergen as one test.

Chemistry profiles: count each individual analyte separately.

Complete blood counts: count each measured individual analyte separately that is ordered and reported separately. Differentials are counted as one test. Manual differentials are counted as a separate test.

Cytogenetics: the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.

Cytology: count each slide (not case) as one test for both pap smears and nongynecologic cytology.

Histocompatibility: count each HLA typing (including disease associated antigens), HLA anti-body screen, or HLA crossmatch as one test.

Histopathology: count each block (not slide) as one test. Autopsy services are not included.

For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains, including immunohistochemistry, performed on slides to the total number of specimen blocks prepared by the laboratory.

Immunohematology: count each ABO, Rh, antibody screen, crossmatch, or antibody identification as separate tests.

Microbiology: count susceptibility testing as one test per group of antibiotics used to determine sensitivity for one organism. Count cultures as one per specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria smear from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test. Count molecular tests as one per specimen.

Urinalysis: count microscopic and macroscopic examinations as separate tests.

Count macroscopics (dipsticks) as one test regardless of the number of reagent pads on the strip.

☐ **Section 7 - Personnel Qualification Requirements:**
Check the option that matches the qualifications of the director for the license you are applying for.

Moderate Complexity Testing: Complete this section if the highest complexity of testing performed is moderate. Courses are available to obtain 20 CE credit hours in laboratory practice. Visit http://www.doh.wa.gov/mts for a list of available courses.

High Complexity Testing: Complete this section if the MTS will perform high complexity tests.

☐ **Section 8 - Signature:**
The legal owner or authorized representative must sign and date the application. Print the name and title of the legal owner or authorized representative.

Please contact Facilities Customer Service at 360-236-4985 if you have any questions or need assistance in completing the application form. Additional information is available on our website at: http://www.doh.wa.gov/mts.

Proficiency Testing
(Not required for Waived or PPMP testing)

Categorized and Accredited Medical Test Sites must enroll in PT for all regulated analytes listed below. Submit a list of your planned enrollments with your application, such as the PT provider and program numbers. Not all proficiency testing will satisfy enrollment requirements, so you must verify that the program you want to enroll in is regulated for proficiency testing. Check the MTS website for a list of currently approved proficiency testing providers.

Each laboratory must enroll in PT in the following tests:

Chemistry
ALT/SGPT
Albumin
Alkaline phosphatase
Amylase
AST/SGOT
B-natriuretic peptide (BNP)
Bilirubin, total (or neonat.)
Blood gas p02, pC02, pH
Calcium, total
Cancer antigen (CA) 125
Carbon dioxide
Carginoembryonic antigen
Chloride
Cholesterol, total
LDL cholesterol, direct
HDL cholesterol
Creatine kinase
Creatine kinase isoen-zymes
Creatinine
Ferritin
GGT
Glucose
Hemoglobin A1c
Iron, total
Total iron binding capacity, direct
LDH
Magnesium
Phosphorus
Potassium
ProBNP
Prostate specific antigen
Sodium
Total protein
Triglycerides
Troponin I
Troponin T
Urea nitrogen
Uric acid

Endocrinology
Cortisol
Estradiol
Free thyroxine
Folate, serum
FSH
Serum pregnancy (HCG) (qualitative or quantitative)
Luteinizing hormone
Parathyroid hormone
Progesterone
Prolactin
Testosterone
T3 uptake
Triiodothyromine
TSH
Thyroxine
Vitamin B12

Toxicology
Acetaminophen, serum
Alcohol, blood
Blood lead
Carbamazepine
Digoxin
Gentamicin
Lithium
Phenobarbital
Phenytoin
Salicylate
Tobramycin
Theophyline
Valproic acid
Vancomycin

Hematology
Cell identification-manual
WBC differential-auto
RBC
Erythrocyte count (RBC)
Hematocrit (automated)
Hemoglobin
WBC
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

Immunohematology
ABO group
D (Rh typing)
Unexpected Antibody detection
Compatibility testing
Antibody identification

Syphilis Serology
Qualitative and Quantitative Syphilis Testing

Immunology
Alpha–1 Antitrypsin
AFP (tumor marker)
Anti-HBs
Anti-HCV
Antinuclear antibody
ASO
C-reactive protein (high sensitivity)
Complement C3, C4
HIV
HBsAg, Anti–HBc, HBeAg
IgA, IgE, IgG, IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

Bacteriology
Gram stain
Detection and ID*
Direct antigen detection
Toxin detection
Antimicrobial susceptibility

Mycobacteriology
Acid-fast stain
Detection and ID*

Mycology
Direct fungal antigen detection
Detection and ID*

Parasitology
Direct antigen detection
Detection and ID*

Virology
Antigen detection
Detection and ID

* Includes detection of presence or absence of organisms, with ID or without

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P.O. Box 1099
Olympia, WA 98507-1099
360-236-4700
http://www.doh.wa.gov/mts

Date Stamp Here

Medical Test Site License Application

Application Type

☐ New License

Anticipated date patient testing will begin (Laboratories may not begin testing until an MTS license is approved and issued): _____

☐ Change of License Type

Previous MTS license number or CLIA number: _____

☐ Change of Ownership

Notification of a change of ownership must be submitted at least thirty days in advance.

Previous owner's MTS license number or CLIA number: _____

Effective Date of Ownership Change: _____

☐ Expired or Closed Reactivation - Previous MTS license or CLIA number: _____

License Type (choose only one):

☐ Waived
☐ Provider Performed Microscopic Procedures (PPMP)
☐ Categorized
☐ Accredited

Submit proof of your application for enrollment to the accreditation organization.

Name of laboratory accreditation organization: _____

Date of application submission to laboratory accreditation organization: _____

Entity Type:

☐ Association
☐ Corporation
☐ Limited Liability Company
☐ Limited Liability Partnership
☐ Limited Partnership
☐ Municipality (City)
☐ Municipality (County)
☐ Non-Profit Corporation
☐ Partnership
☐ Sole Proprietor
☐ State Government Agency
☐ Trust

Section 1. Business Information

UBI #	Federal Employer ID Number (FEIN)
Legal Owner/Operator Entity Name (as it appears on the UBI/Master Business License)	
Mailing Address	

City	State	Zip Code	County

Phone (enter 10 digit #)	Fax (enter 10 digit #)
Email Address	Web Address

Facility/Agency Name (Business name as advertised on signs or website)			
Facility Specific Federal Employer ID Number (FEIN) (if different than one entered above.)			
Physical Address			
City	State	Zip Code	County
Facility Phone (enter 10 digit #)		Facility Fax (enter 10 digit #)	
Mailing Address (If different than physical address)			
City	State	Zip Code	County

Section 2. Facility Specific Information

Site Type (check one only)

___ 1 Ambulance
___ 2 Ambulatory Surgery Center
___ 3 Ancillary Test Site
___ 4 Assisted Living Facility
___ 5 Blood Banks
___ 6 Community Clinic
___ 7 Comprehensive Outpatient Rehab
___ 8 End Stage Renal Disease Dialysis
___ 9 Federally Qualified Health Center
___ 10 Health Fair
___ 11 Health Main. Organization
___ 12 Home Health Agency
___ 13 Hospice
___ 14 Hospital
___ 15 Independent Laboratory
___ 16 Industrial
___ 17 Insurance
___ 18 ICFMR
___ 19 Mobile Lab
___ 20 Pharmacy
___ 21 Physician Office
___ 22 Other Practitioner
___ 23 Prison
___ 24 Public Health Lab
___ 25 Rural Health Clinic
___ 26 Student Health Service
___ 27 Skilled Nursing Facility
___ 28 Tissue Bank/Repository
___ 29 Clinic
___ 30 Drug Treatment
___ 31 Tribal
___ 32 WIC
___ 33 Other _____

Hours of Testing: If testing 24 hours daily, check here ☐

List days and times during which **testing** is performed.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:							
To:							

Additional locations under this license ☐ Yes ☐ No

Applicable only if the medical test site is a not-for-profit or state or local government and performs a combination of 15 or less waived and/or moderate complexity test procedures at different locations.

If yes: Include a copy of your federal 501(c)(3) determination letter and attach a list of names, addresses, phone numbers, and tests performed for each site that will be included under one license.

Foreign Ownership

Is this facility partially or fully owned by a foreign entity or foreign government: ☐ Yes ☐ No

If yes, what is the country of origin for the foreign entity? _____

Testing Complexity - Categorized and Accredited License Applicants ONLY

Indicate the highest complexity level of testing to be performed (choose only one):

☐ Moderate complexity

☐ High complexity

Provide a copy of the medical test site's anticipated PT enrollment (PT provider and all programs).

Section 3. Key Individuals

Lab Director - **This information is required for all applicants.** If the lab director has a professional license, submit a copy of the credential (include MD, PhD, BS, etc.).

First Name	Last Name	WA State Professional License number

Email Address

Does the director of this laboratory serve as director for any other laboratories that are separately licensed in Washington or another state? ☐ Yes ☐ No

If yes, provide the name of the laboratory and CLIA number:

_____

Additional Contact Person - List a second person that can be contacted in the lab director is unavailable

First Name	Last Name	WA State Professional License number

Email Address

Section 4. Waived Test Information

If applying for a certificate of waiver MTS license, complete this section and skip to Section 8 (Signature).

PPMP, Categorized, and Accredited MTS license applicants should complete this section if waived tests will be performed in their laboratory.

Test Name	Test System (e.g. One Step Glucose)	Test Manufacturer (e.g. ACME)
Adenovirus		
Aerobic/Anaerobic Organisms - Vaginal		
Alanine Aminotransferase (ALT) (SGPT)		
Albumin		
Albumin, Urinary		
Alcohol, Saliva		
Alkaline Phosphatase (ALP)		
Amines		
Amphetamines		
Amylase		
Aspartate Aminotransferase (AST) (SGOT)		
Bacteria Associated With Bacterial Vaginosis		
Barbiturates		
Benzodiazepines		
Bilirubin, Total		
Bladder Tumor Associated Antigen		
B-Type Natriuretic Peptide (BNP)		
Buprenorphine		
Calcium, Ionized		
Calcium, Total		
Cannabinoids (THC)		
Carbon Dioxide, Total (CO2)		
Catalase, Urine		
Chlamydia		
Chloride		
Cholesterol		
Cocaine Metabolites		
Collagen Type I Crosslink, N-Telopeptides (NTX)		
Cotinine		
Creatine Kinase (CK)		

Waived Tests (continued)		
Creatinine		
Eddp (Methadone Metabolite)		
Erythrocyte Sedimentation Rate (ESR), Nonautomated		
Estrone-3 Glucuronide		
Ethanol (Alcohol)		
Fecal Occult Blood		
Fentanyl		
Fern Test, Saliva		
Follicle Stimulating Hormone (FSH)		
Fructosamine		
Gamma Glutamyl Transferase (GGT)		
Gastric Occult Blood		
Gastric pH		
Glucose		
Glycated Hemoglobin, Total		
Glycosylated Hemoglobin (HGB A1C)		
hCG, Urine		
HDL Cholesterol		
Helicobacter Pylori		
Helicobacter Pylori Antibodies		
Hematocrit		
Hemoglobin		
Hemoglobin By Copper Sulfate, Nonautomated		
Hepatitis C Virus Antibody		
Herpes Simplex I And/Or II Antibodies		
HIV-1 And HIV-2 Antibodies		
HIV-1 And HIV-2 Antigens		
Infectious Mononucleosis Antibodies (Mono)		
Influenza (A/B)		
Ketone, Blood		
Ketone, Urine		
Lactic Acid (Lactate)		
LDL Cholesterol		
Lead, Blood		
Leukocyte Esterase, Urinary		
Lithium		
Luteinizing Hormone (LH)		
Lyme Disease Antibodies (Borrelia Burgdorferi Abs)		
Matrix Metalloproteinases-9 (MMP-9)		
Methadone		
Methadone Metabolite (EDDP)		
Methamphetamine		
Methylenedioxymethamphetamine (MDMA)		

Waived Tests (continued)		
Microalbumin		
Morphine		
Neisseria Gonorrhoeae		
Neutrophil Percentage (Neut%)		
Nicotine And/Or Metabolites		
Nitrite, Urine		
Norfentanyl		
Nortriptyline		
Opiates		
Osmolality, Tears		
Ovulation Test (LH) By Visual Color Comparison		
Oxazepam		
Oxycodone		
pH		
pH, Urine		
Phencyclidine (PCP)		
Phenobarbital		
Phosphorus		
Platelet Aggregation		
Platelet Count		
Potassium		
Pregnanediol Glucuronide		
Propoxyphene		
Protein, Total		
Prothrombin Time (PT)		
Red Blood Cell Count (Erythrocyte Count) (Rbc)		
Respiratory Bacterial Pathogens		
Respiratory Syncytial Virus		
Respiratory Viruses		
SARS-CoV-2 (COVID)		
SARS-CoV-2 (COVID) And Other Respiratory Viruses		
Secobarbital		
Semen		
Sodium		
Spun Microhematocrit		
Streptococcus, Group A		
Thyroid Stimulating Hormone (TSH)		
Tramadol		
Treponema Pallidum (Syphilis) Antibodies		
Trichomonas		
Tricyclic Antidepressants		

Waived Tests (continued)		
Triglyceride		
Urea (BUN)		
Uric Acid		
Urinary Protein, Qualitative		
Urine Dipstick Or Tablet Analytes, Nonautomated		
Urine hCG By Visual Color Comparison Tests		
Urinalysis		
Vaginal pH		
White Blood Cell Count (Leukocyte Count) (WBC)		
White Blood Cell Differential (WBC Diff)		
Whole Blood Qualitative Dipstick Glucose		
Yeast, Candida Only		
Other Waived Test(S) Not Listed		

Section 5. Provider-Performed Microscopic Procedures (PPMP) Test Information

If applying for a PPMP MTS license, complete this section, then skip to section 8 (Signature).
Categorized and Accredited MTS license applicants should complete this section if PPMP will be performed by an approved provider (WA State licensed MD, DO, DPM, ARNP, PA or Dentist).

Total Volume: _____

__ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
__ Fecal leukocyte examinations
__ Fern tests
__ Nasal Smears for granulocytes
__ Pinworm examinations
__ Post-coital direct, qualitative examinations of vaginal or cervical mucous
__ Potassium hydroxide (KOH) preparations
__ Qualitative semen analysis (limited to the presence/ absence of sperm and detection of motility)
__ Urine sediment examinations

Section 6. Nonwaived Test Information

Complete this section if you are applying for a Categorized or Accredited MTS license.

Refer to the Application Instructions Checklist if you need assistance completing this table and for information about proficiency testing.

Microbiology

Microscopic Procedures

Total Volume: _____

NOTE: If the following microscopic tests are ONLY done by a licensed provider, DO NOT complete this section

___ Wet Mounts

___ Fecal Leukocytes

___ KOH

___ Pinworm

___ Post Coital Vagina Mucous Exam

___ Fern Tests

___ Qualitative Semen Analysis (post vas)

___ Quantitative Semen Analysis

___ Urine Sediment

___ Nasal Smear for Granulocytes

Bacteriology

Total Volume: _____

___ Affirm VP (TV, GV, YST)

___ Antibiotic Sensitivities

___ Bacterial Antigens

- **___ Clostridium difficile**
- **___ Group A Strep) rapid test - nonwaived kits)**
- **___ Group B Strep**

___ Bacterial Toxin Detection

___ Blood Culture

___ Chlamidia

___ CSF Culture

___ Gram Stain

___ GC

___ Throat Culture

___ Urine Culture

___ Urine Colony Count

___ Other Culture/Molecular:_____

Mycobacteriology

Total Volume: _____

___ AFB Smear/Stain

___ AFB Antibiotic Sensitivities

___ AFB Culture & ID

___ Other/Molecular: _____

Mycology

Total Volume: _____

___ DTM Only

___ Direct fungal antigen detection

___ Fungus Culture

- **___ Growth/No Growth**
- **___ Culture and ID**

___ Yeast Culture

- **___ Growth/No Growth**
- **___ Culture and ID**

___ Other/Molecular: _____

Parasitology

Total Volume: _____

___ Direct Smear

___ Concentrate/Stain

___ Parasitic Antigens

___ Other/Molecular: _____

Virology

Total Volume: _____

___ Herpes Antigen

___ Herpes Culture

___ Other Viral Culture

___ Viral Antigen Detection

- ___ Human Papillomavirus (HPV)
- ___ Influenza (nonwaived kits)
- ___ RSV (nonwaived kits)

___ SARS-CoV-2 (nonwaived kits)

___ Other/Molecular: _____

Nonwaived Test Information

Diagnostic Immunology

Syphilis Serology

Total Volume: _____

___ **RPR**

___ **VDRL**

___ **MHA-TP (TP-PA)**

___ **FTA**

General Immunology

Total Volume: _____

___ Allergy Testing (count individual allergens tested)

___ **Alpha-1 Antitrypsin**

___ **AFP/Tumor**

___ **AFP/Other**

___ **ANA**

___ **ASO**

___ **Anti-HCV**

___ **HIV**

___ **C3**

___ **C4**

___ C-reactive protein

___ **C-reactive protein (high sensitivity)**

___ **HBsAg**

___ **Anti-HBc**

___ **Anti-HBs**

___ **HBeAg**

___ **HCV**

___ **IgA**

___ **IgG**

___ **IgE**

___ **IgM**

___ **Infectious Mononucleosis (nonwaived kit)**

___ **Rheumatoid Factor**

___ H. pylori (nonwaived kits)

___ COVID-19 Serology

___ **Rubella Antibody**

___ Other (list): _____

Histocompatibility

Histocompatibility

Total Volume: _____

___ Transplant

___ Nontransplant (list specific tests): _____

Pathology

Pathology

___ Histopathology

- ___ Dermatopathology _____/year
- ___ MOHS cases _____/year
- ___ Special stains _____/year
  (e.g. PAS, trichrome, Iron)
- ___ Predictive IHC _____/year
  (e.g. HER2, PD-L1, ER/PR)
- ___ Prognostic IHC _____/year
  (e.g. Ki-67, p53)
- ___ Other _____/year

___ Oral Pathology _____/year

___ Cytology _____/year

- ___ Gynecological slids
- ___ Non-gynecological slides
- ___ Check if MTS performs final interpretation only

___ FISH _____/year

Radiobioassay

Radiobioassay

Total Volume: _____

_____

(list in vitro tests, i.e. blood volume by Cr 51, Schilling test, etc.)

Do NOT include routine RIA tests

Nonwaived Test Information

Chemistry

Routine Chemistry

Total Volume: _____

NOTE: Each measured parameter must be counted as a separate test, added together, and included in the Routine Chemistry total volume above.

___ **ALT/SGPT**
___ **Albumin**
___ **Alkaline Phosphatase**
___ **Amylase**
___ **AST/SGOT**
___ **Bilirubin, Total/Neonatal**
___ **B-natriuretic peptide (BNP)**
___ **pH (blood gas)**
___ **pCO2 (blood gas)**
___ **pO2 (blood gas)**
___ **Calcium, Total**
___ **Carbon Dioxide**
___ **Chloride**
___ **Cholesterol, Total**
___ Cholinesterase: RBC methodology: _____
plasma/serum methodology: _____
___ **HDL Cholesterol**
___ **LDL-Direct Cholesterol**
___ **Creatine Kinase**
___ **CK Isoenzymes**
___ **Creatinine**
___ **Ferritin**
___ **GGT**
___ **Glucose**
___ **Hemoglobin A1C**
___ **Iron, Total**
___ **LDH**
___ LDH Isoenzymes
___ **Magnesium**
___ Myoglobin
___ **Phosphorus**
___ **Potassium**
___ **ProBNP**
___ **PSA (Prostate specific antigen, total)**
___ **Sodium**
___ **Total iron binding capacity (TIBC), direct**
___ **Total Protein**
___ **Triglycerides**
___ **Troponin I**
___ **Troponin T**
___ **Urea Nitrogen (BUN)**
___ **Uric Acid**
___ Ammonia
___ Bilirubin, direct
___ C-peptide
___ CA 19-9
___ CA 15-3
___ Ceruloplasmin
___ FFN (Fetal Fibronectin)
___ Free PSA
___ Haptoglobin
___ Homocysteine
___ Lactic Acid
___ Lipase
___ Ketones, serum
___ Osmolality
___ Protein Electrophoresis
___ Prealbumin
___ ROM (Rupture of Membranes)
___ Transferrin, direct
___ Vitamin D
___ Other (list): _____

Chemistry (continued)

Urinalysis

Total Volume: _____

___ Strip by nonwaived instrument

Endocrinology

Total Volume: _____

___ **Cancer antigen (CA) 125**

___ **Carcinoembryonic antigen (CEA)**

___ **Cortisol**

___ **Estradiol**

___ **Folate, serum**

___ **FSH**

___ FT3 (Free Triiodothyronine)

___ **FT4 (Free Thyroxine)**

___ **HCG (Serum Pregnancy or nonwaived urine HCG)**

___ **Luteinizing hormone (LH)**

___ **Parathyroid hormone (PTH)**

___ **Progesterone**

___ **Prolactin**

___ **Testosterone**

___ **T3 Uptake**

___ **T3 (Triiodothyronine)**

___ **TSH**

___ **T4 (Thyroxine)**

___ **Vitamin B12**

___ ACTH (Adrenocorticotropic hormone)

___ DHEA-S

___ Insulin

___ Procalcitonin

___ Other (list): _____

Toxicology

Total Volume: _____

___ **Acetaminophen, serum**

___ **Alcohol, Blood**

___ **Carbamazepine**

___ **Digoxin**

___ Ethosuximide

___ **Gentamicin**

___ **Lead, Blood**

___ **Lithium**

___ **Phenobarbital**

___ **Phenytoin**

___ Primidone

___ Procainamide/metabolites

___ Quinidine

___ **Salicylate**

___ **Theophylline**

___ **Tobramycin**

___ **Valproic Acid**

___ **Vancomycin**

___ Drugs of Abuse (urine):

___# of Panels **X** ___# of Analytes = ____Total

___ Fentanyl

___ Tacrolimus

___ Other (list): _____

Nonwaived Test Information

Hematology

Hematology

Total Volume: _____

___ Cell Identification/Manual Differential

CBC (Complete Blood Count):

___ Auto WBC Differential

___ RBC

___ Hematocrit

___ Hemoglobin

___ WBC

___ Platelet Count

Note: Each measured parameter (automated differential, RBC, hematocrit(or MCV), hemoglobin, WBC, platelets) must be counted as a separate test.

___ Reticulocyte Count

___ Hemoglobin Electrophoresis

___ Flow Cytometry

___ ESR (Erythrocyte Sedimentation Rate)

___ Other (list): _____

Coagulation

Total Volume: _____

___ Fibrinogen

___ PTT

___ Prothrombin Time

___ Thrombin Time

___ Factor Assays

___ Activated Clotting Time

___ D-dimer

___ Other (list): _____

Immunohematology

Immunohematology

Total Volume: _____

___ ABO Group_____/year

___ D (Rh) Typing_____/year

___ Antibody Detection (Screen) _____/year

___ Antibody Identification_____/year

___ Compatibility Test (Crossmatch) _____/year

___ Other (list): _____

Transfusion Services

___ Units transfused: _____/year

Genetics

Genetic Testing

Total Volume: _____

____Biochemical Genetic Tests (list tests):

_____

____Cytogenetic Tests (list tests):

_____

____Molecular Genetic Tests (list tests):

_____

NOTE: add HPV testing under Virology, add Chlamydia and/or GC testing under Bacteriology

Section 7. Personnel Qualification Requirements

Categorized or Accredited MTS License Directors

Submit a copy of the director's Washington medical license and board certifications, diploma or transcripts, and third-party verification of the individual's laboratory training and experience. Failure to submit documentation may delay processing of your application.

Moderate Complexity Testing

Complete this section if the MTS will perform moderate complexity tests. If high complexity testing is performed, skip to the next section.

- ☐ Pathologist with WA state license.
- ☐ MD, DO, DPM, with WA state license + 1 year or more directing or supervising nonwaived testing OR 20 CE credit hours in laboratory practice covering director responsibilities.
- ☐ Hold a doctoral degree in a chemical, biological, clinical laboratory science, medical laboratory science or medical technology + have an HHS approved board certification + 1 year or more experience directing or supervising nonwaived laboratory testing.
- ☐ Hold a doctoral degree with at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology, clinical laboratory science, or medical laboratory science + have an HHS approved board certification + 1 year or more experience directing or supervising nonwaived laboratory testing.
- ☐ Hold a doctoral degree and have completed an approved thesis or research project in biology, chemistry, medical technology, clinical laboratory science or medical laboratory science and related to laboratory testing + have an HHS approved board certification + 1 year or more experience directing or supervising nonwaived laboratory testing.
- ☐ Hold a master's degree in a chemical, biological, clinical laboratory science, medical laboratory science or medical technology + 1 year or more of laboratory training or experience in nonwaived testing + 1 year or more of supervisory laboratory experience in nonwaived testing.
- ☐ Meet bachelor's degree equivalency and complete at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical laboratory science or medical laboratory science + 1 year or more of laboratory training or experience in nonwaived testing + 1 year or more of supervisory laboratory experience in nonwaived testing.
- ☐ Meet bachelor's degree equivalency and complete at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical laboratory science or medical laboratory science + an approved thesis or research project related to laboratory testing + 1 year or more of supervisory laboratory experience in nonwaived testing.
- ☐ Hold a bachelor's degree in a chemical, biological, clinical laboratory science, medical laboratory science or medical technology + have 2 years or more of laboratory training or experience in nonwaived testing + 2 years or more of supervisory laboratory experience in nonwaived testing.
- ☐ Complete at least 120 semester hours or equivalent that includes 48 semester hours of clinical or medical laboratory science or medical laboratory technology courses + have 2 years or more of laboratory training or experience in nonwaived testing + 2 years or more of supervisory laboratory experience in nonwaived testing.

☐ Complete at least 120 semester hours or equivalent that includes 48 semester hours of science courses, of which 12 semester hours are general chemistry and biochemistry or organic chemistry and 12 semester hours are general biology, molecular biology and cell biology or genetics and 24 semester hours are chemistry, biology, or medical laboratory science or medical laboratory technology in any combination + have 2 years or more of laboratory training or experience in nonwaived testing + 2 years or more of supervisory laboratory experience in nonwaived testing.

☐ Be qualified as a laboratory director of moderate complexity testing by serving as a laboratory director of moderate complexity testing in a licensed medical test site as of December 28, 2024, and have done so continuously since December 28, 2024.

Technical Consultant – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1411.

Clinical Consultant – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1417.

Testing Personnel – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1423.

High Complexity Testing

Complete this section if the MTS will perform high complexity tests.

☐ Pathologist with WA state license.

☐ MD, DO, DPM, with WA state license + 2 years or more experience directing or supervising high complexity testing.

☐ Hold a doctoral degree in a chemical, biological, clinical laboratory science, medical laboratory science or medical technology + have an HHS approved board certification + have 2 years or more of laboratory training or experience and laboratory experience directing or supervising high complexity testing.

☐ Hold a doctoral degree and have at least 16 semester hours of doctoral level coursework in chemical, biological, clinical laboratory science, medical laboratory science or medical technology + have an HHS approved board certification + have 2 years or more of laboratory training or experience and laboratory experience directing or supervising high complexity testing.

☐ Hold a doctoral degree and complete an approved thesis or research project in biology, chemistry, medical technology, clinical laboratory science, or medical laboratory science and related to laboratory testing + have an HHS approved board certification + have 2 years or more of laboratory training or experience and laboratory experience directing or supervising high complexity testing.

☐ Be qualified as a laboratory director of high complexity testing by serving as a laboratory director of high complexity testing in a licensed medical test site as of December 28, 2024, and have done so continuously since December 28, 2024.

☐ For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or American Osteopathic Board of Pathology.

☐ For the subspecialty of dermatopathology, be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology OR be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology OR be certified in dermatology by the American Board of Dermatology.

Technical Supervisor – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1449.

Clinical Consultant – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1455.

General Supervisor – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1461.

Cytology General Supervisor – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1469, if the subspecialty cytology is performed.

Cytotechnologist – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1483, if the subspecialty cytology is performed.

Testing Personnel – Ensure personnel qualifications are met as described in 42 C.F.R. 493.1489.

Section 8. Signature

I certify that I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify that the information herein submitted is true to the best of my knowledge and belief.

_____ _____

Signature of Owner/Authorized Representative of Medical Test Site Date

_____ _____

Print Name Print Title